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DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

Southwest Import District
4040 N. Central Expressway
Suite 300
Dallas, Texas 75204

WARNING LETTER

Ref: 2002-SWID-WL-3

February 15, 2002

FEDERAL EXPRESS

Fernando Acosta, President
Almacen De Dulce Corporation
909 South Greenwood Avenue
Montebello, CA 90640

Dear Mr. Acosta:

On January 16, 2002, we attempted to examine a shipment of "Patty's Lollipops" offered for import (imported) into the United States by your firm as invoiced and declared to U.S. Customs Service on the same date under entry number EU6-0019205-5. Our examination revealed the actual product to be "Dulmex Brand Hot Tamarind Lollipops." Misrepresenting the product as Patty's Lollipops at the time of entry appears to be an attempt to circumvent our detention without physical examination for products containing tamarind.

In addition, during the time period from 05/07/01 - 07/23/01 we have refused multiple shipments of your products. We have contacted US Customs and it appears that none of these entries have been redelivered for exportation and/or destruction under USCS or FDA supervision as required by the redelivery demands issued to you by US Customs. These entries and the dates redelivery was demanded by US Customs are as follows: Entry Numbers 965-0073049-2, redelivery demanded 5/15/01; 965-0073256-3, redelivery demanded 5/2/01; 965-0073326-4, redelivery demanded 5/24/01; 965-0073497-3, redelivery demanded 5/24/01; 965-0073784-4, redelivery demanded 6/7/01; 965-0074143-2, redelivery demanded 6/27/01; 965-0074309-9, redelivery demanded 9/20/01; 965-0074310-7, redelivery demanded 8/1/01; and 9650074486-5, redelivery demanded 9/20/01. It appears that these entries have been distributed into U.S. commerce without FDA release. This is a violation of 21 USC 381(a) and 21 CFR Section 1.90 that requires an importer to hold an imported article and not distribute it pending receipt of the results of examination. In conjunction with this letter, we are requesting that US Customs assess liquidated damages for failure to redeliver the entries noted above.

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Mr. Acosta

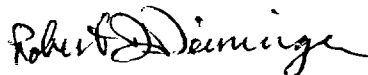
We have also recommended that the U.S. Customs Service require that future shipments of food imported by your firm be held in secured storage. Secured storage will be under the supervision and direction of U.S. Customs, such as in a bonded warehouse. You will be responsible for all costs incurred at secured storage.

Within 15 working days of receipt of this letter, notify this office in writing of the specific steps you have taken to prevent recurrence.

Your reply should be addressed to: Vincent F. Iacono, Compliance Officer
U.S. Food and Drug Administration
Otay Mesa Port of Entry
9777 Via De La Amistad #131
San Diego, CA 92154

Should you have any questions related to this letter, you may also contact Mr. Iacono at 619-661-3273 ex 229.

Sincerely,

A handwritten signature in black ink, appearing to read "Robert J. Deininger".

Robert J. Deininger
Southwest Import District
District Director

O: Addressee via Fed Express